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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/472,232
Filing Date: December 27, 1999
Appellant(s): DUMAS ET AL.

Richard J. Traverso

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 10, 2006 appealing from the Office action mailed April 11, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Simone, Oncology: Introduction, Cecil Textbook of Medicine, 20th Edition, Vol. 1, pp. 1004-1010, 1996.

Monia et al., "Antitumor activity of a phosphorothioate antisense oligodeopxynucleotide targeted against C-raf kinase", Nature Medicine, Vol. 2, No. 6, (June 1996) pp. 668-75.

Kolch et al., "Raf-1 protein kinase is required for growth of induced NIH/3T3 cells", Letters to Nature, Vol. 349 (January 31, 1991) pp. 226-28.

6,080,763 REGAN 6-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. 112

1. Claims 15-16, 18-23, 26-29 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cancer of the colon, does not reasonably provide enablement for the treatment of all other diseases of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to the treatment of 'disease mediated by raf kinase' and according to the specification, the compounds are useful in the treatment of tumors and/or

cancerous cell growth mediated by raf kinase, see specification page 2, lines 5-17. Further, the specification discloses several types of cancers, e.g., solid cancers, myeloid disorders, adenomas. First, the instant claims cover 'diseases' that are known to exist and those that may be discovered in the future, for which there is no enablement provided. Further, no compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "silver bullet" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states that "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body. Also see *In re Buting*, 163 USPQ 689 (CCPA 1969), wherein "evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers". Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers and/or diseases mediated by raf kinase in general.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: Therapeutic use of the compounds in treating diseases mediated by raf kinase which includes tumors and/or cancerous cell growth.

2) The state of the prior art: There are no known compounds of similar structure, which have been demonstrated to treat all types of cancers.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present and 5) the presence or absence of working examples: There are no doses present to direct one to protect a potential host from the disorders embraced by the instant claims nor there are doses given for the treatment of the disorders recited. The specification provides assays (see pages 33-35) to test the compounds *in vitro* and discloses that the compounds exhibit raf kinase inhibitory properties. However, no *in vivo* test procedures or data provided for the compounds commensurate in scope of the claims and there is no disclosure regarding how the *in vitro* results correlate to *in vivo* tests. *In vivo* test procedures are provided for the cancers of the colon in mice (see page 35), however, there is no demonstrated correlation that the tests and results apply to all of the disorders embraced by the instant claims.

6) The breadth of the claims: The instant claims embrace the treatment of all diseases mediated by raf kinase. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

7) The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 U.S.C. 103

2. Claims 1-2, 4-6, 9-10, 18-24, 26-31, 38 and 40 are rejected under 35 U.S.C. 103(a) as obvious over Regan et al., U.S. Patent No. 6,080,763. The reference teaches a generic group of compounds, which embraces applicant's instantly claimed compounds. See formula (I) in col. 6 wherein the heteroaryl ring represented by ABDEG is a pyrazolyl ring as shown in the examples; Y is –NH-; X is O; and R_5 is phenyl, naphthyl, etc. which is further substituted by one to five substituents which substituent list includes alkyl, halo, cyano, phenyloxy, naphthyloxy, phenylamino, naphthylamino, etc. Further, the reference discloses many examples, see Table 1, wherein Het is A; R_3 is optionally substituted phenyl and R_5 is optionally substituted phenyl. The compounds are taught to be useful as pharmaceutical therapeutic agents, see the abstract. The instant claims differ from the reference by reciting a specific species and/or a more limited

genus than the reference. Specifically, the instant claims differ by requiring a substituent –M-L^1 on the aromatic ring represented by B. The reference discloses several compounds wherein the phenyl ring at the analogous position is substituted by halo, cyano, methoxy, etc. and further teaches the equivalence of substituents alkyl, halo, cyano, phenyloxy, naphthyloxy, phenylamino, naphthylamino, etc. as these substituents are disclosed to be alternatives to be substituted on the aromatic ring. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have had the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

(10) Response to Argument

Claim Rejections - 35 U.S.C. 112

Appellant's arguments have been fully considered but they were not deemed to be persuasive. Appellant first asserts that 'the specification provides a number of publications that have correlated the inhibition of RAF kinase with the inhibition of the growth of a variety of

tumor types'. However, contrary to applicant's assertion, the state of the art references do not establish a therapeutic method for the treatment of cancerous cell growth mediated by RAF kinase generally. See e.g., Kolch (Nature 1991) provides that RAF-1 inhibitors blocked proliferation of specific oncogenes. Monia (Nat. Med. 1996) also provided a role of RAF kinase in the development of specific types of malignancies. None of the state of the art references of record expressed a single therapeutic approach for 'the treatment of a disease mediated by raf kinase' generally by administering a single class of compounds. Further, the state of the art is not indicative of the fact that treatment of all types of diseases mediated by RAF kinase or treatment of solid cancer, melanoma or adenoma is conventional or well known. The cited references are too speculative. The references are specific with respect to limited types of cancerous growth or malignancy.

Appellant argues that 'no evidence has been presented to refute the findings or conclusions made in the publications'. However, as explained above, the findings and conclusions in the cited publications with respect to inhibition of RAF kinase and the application of such activity for specific types of cancerous growth. The instant claims, on the other hand, are drawn to several types of diseases or cancers affecting different organs and having different methods of growth or harm to the body, and different vulnerabilities. The development of the most efficacious strategy for the treatment of cancers is based on understanding the underlying mechanisms of carcinogenesis. This includes the knowledge that the carcinogenic process is a multi-step, multi-mechanism process and that no two cancers are alike, in spite of some apparent universal characteristics, such as their inability to have growth control, to terminally differentiate, to apoptose abnormally and to have an apparent extended or immortalized life span.

Since tumor promotion phase involves multiple mechanisms, there is no existence of a single therapeutic approach. The instant claims recite 'a method for treating a solid cancer, melanoma or adenoma' as some of the diseases 'mediated by RAF kinase', however, the art does not identify a single class of compounds that can treat all these types of cancers generally.

Further, one skilled in the art of cancer therapy recognizes that there are complex interactions between individual genetic, developmental state, sex, dietary, environmental, drug, and lifestyle factors that contribute to the carcinogenic process, making it even more challenging to have a single therapeutic agent for the treatment of diverse cancers. For example, breast cancer is quite different from liver cancer and even not all breast cancers are identical to each other. Rigorously planned and executed clinical trials, incorporating measurement of appropriate biomarkers and pharmacodynamic endpoints are critical for selecting the optimal dose and schedule. A detailed understanding of the molecular mode of action of the RAF kinase inhibitors alongside the elucidation of the molecular pathology of individual cancers is required to identify tumor types and individual patients that may benefit most from treatment. It is also important to construct a pharmacologic audit trail linking molecular biomarkers and pharmacokinetic and pharmacodynamic parameters to tumor response endpoints. There are cancers where the skill level is high and there are multiple successful chemotherapeutic treatments. For many cancers, chemotherapy just does not improve the survival rate. Some of these are colorectal, gastric, pancreatic, bladder, breast, ovarian, cervical and corpus uteri, head and neck. This establishes the difficulties involved in selecting the treatment options of cancers. The various references of record have been fully considered, however, it is maintained that appellants have not provided

sufficient test assays or data to support the method of treatment commensurate in scope with the claims, as of the filing date of the application.

Appellants next direct attention to specification pages 10-13 and argue that 'it would at most involve routine experimentation for one of ordinary skill in the art to treat any one of the diseases mediated by raf kinase or the specific cancers, with a compound of the invention'. However, the specification does not enable any physician skilled in the art of medicine, to use the compound of the invention commensurate in scope with the claims. The specification broadly describes administration procedures and ranges of dosage regimen, however, it is indicated that the method of administration and/or the dose levels depend on a number of factors, which have to be evaluated by one of ordinary skill in the art. These factors include a) determining which of the claimed compounds would treat any particular claimed disease; b) synthesize the compound; c) formulate into a suitable dosage form depending the type of administration method; and d) conduct clinical trials or test the compound in an assay known to be correlated to clinical efficacy of such treatment. The specification pages 33-35 provide assays to determine the activity of the compounds, however, appellants have not asserted that it is art recognized that the assays are correlated to clinical efficacy for treatment of all types of diseases mediated by RAF kinase. There is no working example of treatment of any disease in man or animal. The state of the clinical arts in does not provide any chemotherapeutic agent which effective against cancers in general or the diseases mediated by RAF kinase. There is no known chemotherapeutic drug, which would target and destroy only cancer cells without adverse effects or toxicities on normal cells.

Appellants argue that 'the specification provides sufficient disclosure to satisfy the requirements of 35 USC § 112 for claims 15-19 and 28-33'. However, the recitation "**disease**" is understood for 'an abnormal condition that impairs normal physiological functioning' (as per Webster's) and the instant claims include diseases other than cancers and there is nothing in the specification regarding what these diseases are. The instant claims appear to be 'reach through' claims. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention. Further, the test procedures and data of the specification are drawn to the inhibition of oncogenic cell growth. There is nothing on the record to enable one skilled in the art to use the compounds in the treatment of all diseases mediated by raf kinase nor the does the record identify which diseases are contemplated. The dosage regimen at page 16 of the specification is fully considered, however, the disclosure does not provide sufficient guidance or direction towards treatment of all 'diseases' mediated by raf kinase. As submitted by the applicant, 'the particular method of administration will depend on a variety of factors' (see page 16, lines 31-32) and the instant application does not provide reasonable explanation of the 'diseases mediated raf kinase' within the scope of the claims and therefore, it will be undue burden on the skilled artisan to evaluate the diseases and further the variety of factors required to adopt the dosage regimen.

Appellants cite several case laws and argue that the enablement requirement is satisfied. This is not seen to be the case. For example, contrary to what appellants urge by citing *In re Marzocchi*,169 USPQ 367, the examiner has provided both reasoning including the nature of the

invention which is directed to an unpredictable art, citation of case law as well as relevant publication to support the reason for the rejection. Appellants have not identified any state of the art references that clearly establish correlation between the assays employed in the specification and clinical efficacy for the treatment of the claimed diseases. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of *in vivo* efficacy by those skilled in the art. See for example *In re Ruskin* 148 USPQ 221; *Ex parte Jovanovics* 211 USPQ 907.

Appellants cite *In re Brana* and argue that 'the specification provides *in vitro* and *in vivo* assays (in pages 33-34) based on which one of ordinary skill in the art can determine the activity of each of the claimed compounds in treating various diseases mediated by raf kinase or the various cancers. Appellant's reliance on the *Brana* decision is erroneous since the facts were different in more than one respect from the instant case. Compounds on appeal were of a much narrower scope and there were no method claims. Said compounds were similar in structure to compounds displaying *in vivo* anti-tumor activity based on art-recognized *in vivo* tests and also tested favorably in an *in vivo* test. Thus, contrary to *Brana* it is not evident that at the time of appellant's effective filing that raf kinase inhibitors having such a diversity of susbtituents on analogous urea compounds are well known for treating cancers urged treatable based simply on assay testing relied on herein.

Based on the fact situation of the instant application, *In re Buting*, 163 USPQ 689 (CCPA 1969) (cited in the previous office actions) is on point and more applicable to the instant claims wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers. The judges in that case

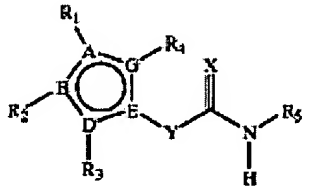
indicated that "We are not aware of any reputable authority which would accept appellant's two clinical cases as establishing utility for treatment of cancer in humans. As was pointed out in *Brenner v. Manson*, 148 USPQ 689, a process to be patentable must produce a useful result and be of substantial utility not merely of scientific interest or for further testing. In this case further testing seems necessary".

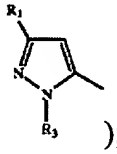
In summary, appellants have not provided any evidence of record that the instantly claimed compounds can effectively be used in the treatment of all types of cancers mediated by raf kinase and therefore, it is maintained that one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 U.S.C. 103

Appellant first argues that 'the reference does not suggest any of the compounds of the instant claims'. This is not found to be persuasive. The reference generically teaches compounds of structural formula:

(I)



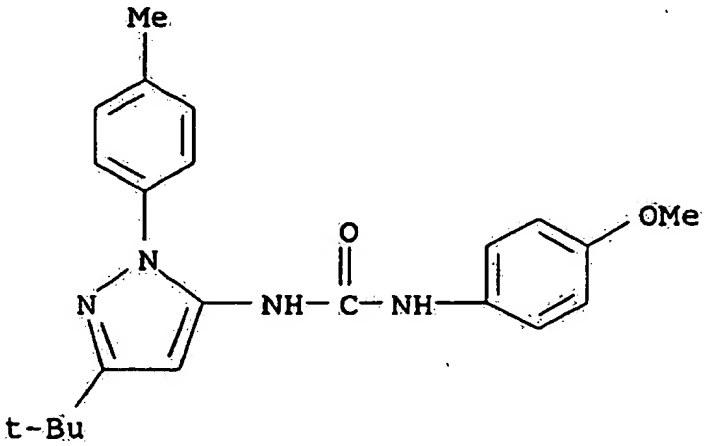


wherein the ring containing ABDEG is a pyrazolyl (i.e.,); Y is NH;

X is O; and

R_5 is phenyl, naphthyl, or heteroaryl which is substituted by substituents selected from alkyl, cycloalkyl, halo, cyano, alkoxy, phenyloxy, naphthyloxy, nitro, amino, alkylamino, phenylamino, naphthylamino, etc.

The reference further discloses several species wherein the ABDEG ring is a pyrazolyl, see for example, the following species (Table 1, Example 18):



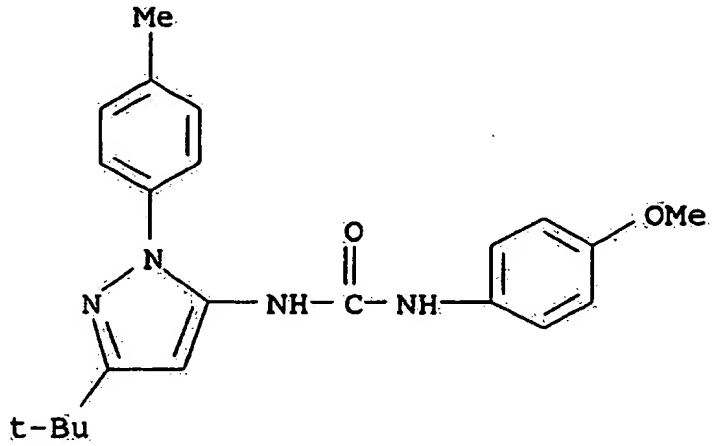
The instantly claimed compounds differ by requiring a substituent –M-L^1 on the terminal phenyl group, wherein M is –O-, -S-, etc. and L^1 is a 5-10 member aromatic structure, e.g., a phenyl. However, the reference teaches that the phenyl group of R_5 is further substituted with substituents such as alkyl, halo, cyano, alkoxy, phenyloxy, naphthyloxy, etc. The reference teaches the equivalence of the various substituents as they are taught to be alternatives for substitution on the aromatic cyclic groups. Further, the reference discloses compounds wherein the phenyl (R_5) is substituted by methoxy, cyano, fluoro, etc. and therefore, provides sufficient motivation to one of ordinary skill in the art to prepare compounds using another substituent on the phenyl ring which is taught to be equivalent. Thus, the reference provides sufficient

motivation for the ordinary artisan to modify the reference compounds to arrive at the instantly claimed compounds because one of ordinary skill in the art only needs to make one change to the reference disclosed compound, i.e., replacing one substituent with another, to arrive at the instantly claimed compound. Therefore, contrary to appellant's arguments, the reference clearly teaches compounds that are structurally analogous to the instantly claimed compounds and thus, the reference provides sufficient motivation to one of ordinary skill in the art to prepare compounds having the bridged cyclic group (-M-L^1).

Appellants cite *In re Jones* to overcome the obviousness rejection. However, *Jones* dealt with the obviousness of a particular claimed ammonium salt based on a generic teaching of "substituted ammonium salts" with no Markush recitation for particular moiety, aminoethoxy ethanol, the salt on appeal. Secondary references applied in *Jones* were deemed not properly combinable with the generic disclosure in the primary reference since the references were not all from the same art area. Unlike the situation in *Jones*, the instantly claimed compounds are expressly taught in a single reference (Regan), which generically discloses all the elements of the instantly claimed genus and/or species. Thus, the reference provides sufficient motivation for the ordinary artisan to modify the reference compounds to arrive at the instantly claimed compounds because one of ordinary skill in the art only needs to make one change to the reference disclosed compound to arrive at the instantly claimed compound.

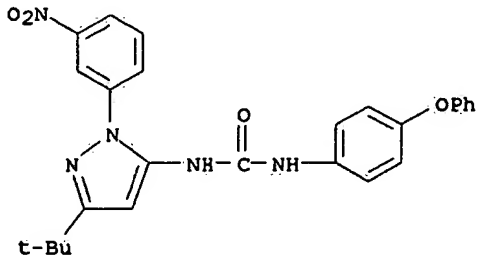
Appellant submits that 'the generic disclosure of Regan includes bridged cyclic substituents' (see page 10 of the appeal brief), however, argues that 'one skilled in the art would need to make more than one selection of variables to arrive at the claimed compounds'. This is not persuasive because the reference teaches several pyrazole urea compounds, see the

compounds disclosed in Table 1 wherein Het is A and R_5 is a substituted aromatic cyclic group. The reference further provides motivation to one skilled in the art to prepare pyrazole urea compounds by replacing the substituent on the terminal phenyl group (R_5) with another generically disclosed substituent, which substituents include phenyloxy, phenylamino, etc. as submitted by the appellants. In other words, one skilled in the art needs to make one change to the reference disclosed compound, for example, the compound of Example 18 (depicted below for convenience):

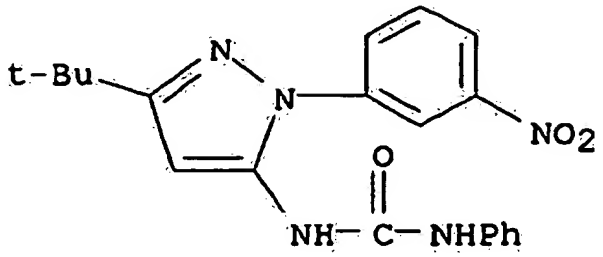


i.e., replace the –OMe with a –O-Ph group to arrive at the instantly claimed compounds. The reference teaches these substituents to be equivalent as they are disclosed to alternatives, and thus entails the motivation to one skilled in the art to make the claimed compounds.

Appellant further argues that 'there is no direction from Regan to arrive at the compounds of claim 40'. This is not persuasive. A compound according to claim 40 has the following structure (third compound):



The reference disclosed compounds include the following species (see Table 1, Ex. No. 34):



As can be seen from the above two structures, the compound according to claim 40 differs from the reference disclosed compound by having a –OPh substituent on the phenyl group. The reference however, teaches the equivalency of unsubstituted phenyl and phenyl substituted with substituents selected from halo, cyano, nitro, alkyl, alkoxy, phenoxy (i.e., -OPh), etc. and therefore, provides sufficient motivation to one skilled in the art to make the instantly claimed compounds from the reference generic disclosure, in the expectation that compounds similar in structure will have similar properties. Thus, the reference teaches structurally analogous compounds which are disclosed to be useful as therapeutic agents. Therefore, motivation exists to prepare other structurally analogous compounds from the prior art disclosed genus. Such structural analogs of the reference compounds would have been obvious to one of ordinary skill in the art because the skilled chemist would have had the reasonable expectation of obtaining compounds having similar properties, i.e., pharmaceutical therapeutic agents. Reference must be considered, under 35 U.S.C. 103, not only for what it expressly teaches but also for what it fairly suggests; all disclosures of prior art, including unpreferred embodiments, must be considered in determining obviousness. *In re Burckel*, 201 USPQ 67 (CCPA 1979).

Appellants argue that the reference compounds are described to be 'useful for treating diseases and pathological conditions involving inflammation and there is no suggestion that the compounds are useful in treating raf mediated diseases'. The instant claim 15 recites 'method for the treatment of disease mediated by raf kinase' and the specification discloses that such diseases include tumors and cancerous cell growth (see page 2). Analogously, the reference also discloses that the reference compounds have therapeutic effect on various diseases of mammal through the inhibitory activity on variety of inflammatory cytokines such as IL-1, IFNγ, etc. which diseases include oncological diseases (see col. 3); multiple myeloma (see col. 5), etc. The reference also indicates that 'cytokines stimulate proliferation' and the compounds of the invention inhibit the release of cytokines. Further, the reference teaches that IFNγ is implicated in a number of diseases, including cancers, and cancers generally include any proliferation of cells, which results in unregulated growth.

It is to be noted that rejection under 35 U.S.C. 103 is proper where the subject matter claimed "is not *identically* disclosed or described" in the prior art, and the prior art directs those skilled in the art to the compounds, without any need for picking, choosing, and combining various disclosures. See *In re Shaumann et al.*, 572 F.2d 312, 315, 316, 197 USPQ 5, 8, (CCPA 1978). Where the specific compound falls within the ambit of a "very limited number of compounds", the fact that a specific embodiment is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered." *In re Lamberti*, 545 F.2d 747,750, 192 USPQ 278, 280 (CCPA 1976). "The question under 35 U.S.C. 103 is not merely what the reference expressly teaches but what it would have suggested to one of ordinary skill in the art at the time the invention was made."

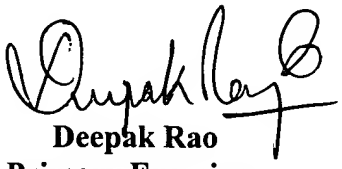
"Structural relationships provide the requisite motivation or suggestion to modify known compounds to obtain new compounds." See *In re Duel*, 51 F.3d at 1558, 34 USPQ2d at 1214. The closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus. See *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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May 25, 2006

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